

1 SPLIT RING BONE SCREW FOR A SPINAL FIXATION SYSTEM

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3 This application is a continuation in part of application
4 Serial Number 09/981,961, filed October 17, 2001.
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6 Field of the Invention

7 This invention is directed to spinal implant systems and,
8 in particular, to a multi-component adjustable implant system
9 capable of maintaining a desired spacial relationship among the
10 bones of a patient's spine.
11

12 Background of the Invention

13 This application provides improvements to the articulating
14 toggle bolt bone screw disclosed in U. S. Patent No.
15 5,628,740, issued to Mullane on May 13,1997 and U. S. Patent
16 No. 6,050,997 issued to Mullane on April 18, 2000. The
17 contents of those patents are hereby incorporated by reference.

18 For individuals with spinal pathologies, the development
19 of spinal fixation devices represents a major medical
20 breakthrough. Surgically implanted fixation systems are
21 commonly used to correct a variety of back structure problems,
22 including those which occur as a result of trauma or improper
23 development during growth. These fixation systems typically
24 include one or more stabilizing rods aligned in a desired

1 orientation with respect to a patient's spine. Additionally,
2 anchoring screws are inserted into the patient's spinal bones,
3 and a series of connectors is used to rigidly link the rods and
4 anchors.

5 A variety of designs exist, with each design addressing
6 various aspects of the difficulties that arise when one re-
7 shapes an individual's spine to follow a preferred curvature.
8 Unfortunately, known spinal implant systems often correct one
9 set of problems only to create new ones.

10 Common to spinal implant systems is the necessity for
11 proper anchoring to the bone so as to provide support for the
12 aforementioned components. While bone screws are commonly used
13 for anchoring, they are limited in their positioning due to the
14 design of component pieces. Numerous patents are directed to
15 component design in order to accommodate the bone screw, yet
16 few patents are directed to bone screws that will accommodate
17 existing component design. In many instances the combination
18 of existing component design and bone screw design inhibits
19 application to a particular spinal injury. For example, bone
20 structure of the sacrum is typically soft, and often
21 osteoporotic in the elderly. Perpendicular placement of a bone
22 screw therein may not be possible and placement at an angle
23 thereto may cause undue stress further affecting adjoining
24 bones. Thus, if a common bone screw is employed, the component

1 connector will be of special design.

2 For this and other reasons, screws located in bone
3 structure typically use a specially designed clamp to attach to
4 a component such as an alignment rod. A problem with specially
5 designed clamps is that bone structure cannot be determined
6 until the patient's bone is exposed causing the necessity of a
7 large inventory of various sized clamps to be on hand during
8 surgery, of which the surgeon must search to find the right
9 combination. Even if a clamp combination is predicted,
10 insertion of the screw may still require angular insertion due
11 to muscle or tender nerve locations. The result is a bone
12 screw which exerts unpredictable forces upon attachment to
13 component connectors. Further, any movement of muscle and
14 other tissue increases the difficulty of the operation and can
15 be a major trauma to a person.

16 A conventional bone screw consists of a single shaft with
17 a coarse thread at one end for threading into the bone and a
18 machine thread at the other end for coupling to components.
19 Another type of bone screw has a U-shaped top which acts as a
20 saddle for attachment to an alignment rod. If the screw is
21 placed incorrectly for any reason, the rod clamp must be made
22 to accommodate the position.

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1 A number of patents exist which demonstrate the reliance
2 on the saddle type screw support and various designs to
3 accommodate the problem.

4 U.S. Patent No. 5,133,717 sets forth a sacral screw with
5 a saddle support. Disclosed is the use of an auxiliary angled
6 screw to provide the necessary support in placing the screw in
7 an angular position for improved anchoring.

8 U.S. Patent No. 5,129,900 sets forth an attachment screw
9 and connector member that is adjustably fastened to an
10 alignment rod. An oblong area provided within each connector
11 member allows minute displacement of the alignment rod.

12 U.S. Patent 4,887,595 discloses a screw that has a first
13 externally threaded portion for engagement with the bone and a
14 second externally threaded portion for engagement with a
15 locking nut. The disclosure illustrates the use of a singular
16 fixed shaft.

17 U.S. Patent 4,946,458 discloses a screw which employs a
18 spherical portion which is adapted to receive a locking pin so
19 as to allow one portion of the screw to rotate around the
20 spherical portion. A problem with the screw is the need for
21 the locking pin and the inability of the base screw to
22 accommodate a threaded extension bolt.

23 U.S. Patent 5,002,542 discloses a screw clamp wherein two
24 horizontally disposed sections are adapted to receive the head

1 of a pedicle screw for use in combination with a hook which
2 holds a support rod at an adjustable distance.

3 U.S. Patent 4,854,304 discloses the use of a screw with a
4 top portion that is adaptable for use with a specially designed
5 alignment rod to permit compression as well as distraction.

6 U.S. Patent 4,887,596 discloses a pedicle screw for use in
7 coupling an alignment rod to the spine wherein the screw
8 includes a clamp permitting adjustment of the angle between the
9 alignment rod and the screw.

10 U.S. Patent 4,836,196 discloses a screw with an upper
11 portion design for threadingly engaging a semi-spherical cup
12 for use with a specially designed alignment rod. The alignment
13 rod having spaced apart covertures for receipt of a spherical
14 disc allowing a support rod to be placed at angular positions.

15 U.S. Patent 5,800,435 sets forth a modular spinal plate
16 assembly for use with polyaxial pedicle screw implant devices.
17 The device includes compressible components that cooperatively
18 lock the device along included rails.

19 U.S. Patent 5,591,166 discloses an orthopedic bone bolt
20 and bone plate construction including a bone plate member and
21 a collection of fasteners. At least one of the fasteners
22 allows for multi-angle mounting configurations. The fasteners
23 also include threaded portions configured to engage a patient's
24 bone tissue.

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1 U.S. Patent 5,569,247 discloses a multi-angle fastener
2 usable for connecting patient bone to other surgical implant
3 components. The '247 device includes fastening bolts having
4 spherical, multi-piece heads that allow for adjustment during
5 installation of the device.

6 U.S. Patent 5,716,357 discloses a spinal treatment and
7 long bone fixation apparatus. The apparatus includes link
8 members adapted to engage patient vertebrae. The link members
9 may be attached in a chain-like fashion to connect bones in a
10 non-linear arrangement. The apparatus also includes at least
11 one multi-directional attachment member for joining the link
12 members. This allows the apparatus to be used in forming a
13 spinal implant fixation system.

14 Another type of spinal fixation system includes rigid
15 screws that engage the posterior region of a patient's spine.
16 The screws are adapted with rod-engaging free ends to engage a
17 support rod that has been formed into a desired spine-
18 curvature-correcting orientation. Clamping members are often
19 used to lock the rod in place with respect to the screws.
20 Instead of clamping members, other fixation systems, such as
21 that disclosed in United States Patent No. 5,129,900, employ
22 connectors that join the support rods and anchoring screws.
23 The connectors eliminate unwanted relative motion between the
24 rod and the screws, thereby maintaining the patient's spine in

1 a corrected orientation.

2 Unfortunately, although these so-called "rigid screw"
3 fixation systems can alter the curvature of a patient's spine,
4 they can also be difficult to install. In this type of system,
5 the anchoring screws must be secured in a region that is
6 strong/rigid enough to support the characteristically-large
7 loads typically transferred from the support rods. As a
8 result, the number of suitable anchoring locations is limited.

9 Typically, these screws are anchored into the posterior region
10 of a patient's spinal column or into pedicle bone. With rigid
11 screw systems, installation requires bending a support rod into
12 a path that will not only correct the shape a patient's spine
13 but that will also engage each of the installed anchoring
14 screws. Achieving a proper fit between all of the components
15 while contending with the constraints encountered during
16 surgery is often difficult. In severe cases, a suitable fit
17 may not be achieved and the surgery will be unsuccessful.

18 Additionally, the nature of the installation process
19 required for rigid screw fixation systems often subjects the
20 system components to pre-loading that unduly stresses the
21 interface between the patient's bone and the employed anchoring
22 screws. With these designs, as a patient moves about during
23 daily life, the system components may become separated from the
24 supporting bone. Corrective surgery to reattach anchoring

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1 screws exposes an already-weakened region to additional trauma
2 and presents the risk of additional damage.

3 Other spinal fixation systems employ adjustable
4 components. For example, United States Patent No. 5,549,608
5 includes anchoring screws that have pivoting free ends which
6 attach to discrete rod-engaging couplers. As a result, the
7 relative position of the anchoring screws and rods may be
8 adjusted to achieve a proper fit, even after the screw has been
9 anchored into a patient's spinal bone. This type of fixation
10 system succeeds in easing the rod-and-screw-linking process.
11 This adjustment capability allows the screws to accommodate
12 several rod paths. Unfortunately, some adjustable fixation
13 systems tolerate only limited amounts of relative adjustment
14 between components, operating best when loaded in one of
15 several preferred arrangements. As a result, many prior art
16 adjustable fixation systems are suitable for only a few
17 situations.

18 Additionally, many adjustable fixation systems are prone
19 to post-surgery component loosening. As a patient moves about
20 during day-to-day living, his spine is subjected to a
21 seemingly-endless amount of dynamic loading. Almost all
22 activity requires some form of back motion; over time, this
23 cyclic movement tends to work the components of many adjustable
24 fixation systems loose.

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1 Some adjustable spinal fixation systems include locking
2 mechanisms designed for long-term, post-surgery securement of
3 the system components. Although capable of being locked in
4 place, these systems are often difficult to secure, requiring
5 an excess of tools during the installation process. The need
6 for extra tools, such as those required to shave or crimp key
7 portions of a fixation system, increasing surgical risk by
8 adding complexity and increasing the number of required steps.
9 Although locking-component fixation systems exist, many of them
10 unduly increase the dangers of back implant surgery to an
11 unacceptable level.

12 Hardware-intensive fasteners are disclosed in United
13 States Patent No. 5,549,608, in which anchoring screws are
14 fitted with wrenching flats that allow an anchoring screw to be
15 attached to a patient's spinal bone with the flats being
16 trimmed away once the screw is in place. Clamping nuts are
17 then used to secure the anchoring screws to included
18 stabilizing rods.

19 Additionally, many spinal fixation systems do not permit
20 component repairs. If, for example, a threaded portion of a
21 connecting member becomes stripped or cross-threaded, the
22 entire connector must be slid off of the associated stabilizing
23 rod. Often, such removal produces an undesirable "domino-
24 effect," requiring that several connectors be slid off to allow

1 removal of the damaged connector. Such requirements add
2 unnecessary difficulty to an already-complex procedure.

3 The bone screws shown and described in U. S. Patent No.
4 5,628,740 and U. S. Patent No. 6,050,997 have a bone screw
5 with a spherical cavity in the proximal end. A toggle bolt
6 with a spherical distal end is inserted into the cavity in the
7 bone screw. A collet is forced into the spherical cavity
8 superior to the spherical end of the toggle bolt. A support
9 collar or attachment cap is placed over the toggle bolt and
10 tightened down. This forces the retention collet to engage the
11 spherical portion of the toggle bolt and the inside of the
12 spherical cavity locking the toggle bolt in a selected angular
13 disposition. This system requires extremely accurate machining
14 of the threaded components to result in an optimum frictional
15 fit. Further, because the collet is a ring, with a fixed inner
16 diameter, there is only one correct size for the spherical
17 components. Finally, any deformation of the ring will lessen
18 the over-all frictional contact by creating wrinkles or ridges
19 on the collet.

20 U. S. Patent No. 5,876,459 to Powell teaches the use of
21 a deformable collet to form a friction lock between components
22 of an artificial hip. The collet is expanded outwardly to
23 frictionally fix an artificial trochanter onto the neck of a
24 ball joint.

1 U. S. Patent No. 4,419,026 to Leto discloses a split
2 ring camming internal locking device used with telescoping
3 tubular members for transporting liquids. The ring is split
4 for flexing to fit around the internal tube and for resiliently
5 sealing against the external tube.

6 Thus, what is needed is a spinal fixation system that
7 includes the advantages of known devices, while addressing the
8 shortcomings they exhibit. The system should allow component
9 adjustment during installation, thereby enabling satisfactory
10 correction of a wide variety of spinal deformities. The system
11 should also include a component locking mechanism that is
12 simple and reliable. The system should include two-piece
13 connectors that may be mounted along a support rod, in-between
14 previously-secured connectors. The system should also include
15 mounting hardware that secures with a minimum of tools and that
16 allows modular replacement of components damaged during
17 installation.

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1 Summary of the Invention

2 The present invention is a bone screw for use in a spinal
3 fixation system for reshaping the spine of a patient. The bone
4 screw has threads on one end for anchoring in the spine. The
5 other end has a spherical connector with a rounded exterior and
6 a ball-shaped cavity therein. The cavity has a larger diameter
7 equator and a narrower mouth. The mouth of the ball-shaped
8 cavity accepts the tapered end of a toggle bolt such that the
9 toggle bolt and the bone screw are connected by a ball joint.
10 The tapered end of the toggle bolt tapers from a larger end
11 toward a narrower threaded shank. To prevent disassembly of
12 the bone screw and toggle bolt, an associated split retention
13 ring locking mechanism is inserted in the ball-shaped cavity
14 between the tapered end of the toggle bolt and the mouth of the
15 cavity. The resilient split retention ring has a spherical
16 outer surface and a tapered aperture therethrough. The taper
17 of the aperture is complimentary to the taper of the toggle
18 bolt. The tapered end of the toggle bolt is inserted through
19 the split retention ring. The ring can be compressed to reduce
20 it's diameter for insertion through the narrower mouth of the
21 cavity and then expands to fill the ball-shaped cavity about
22 the tapered end of the toggle bolt.

23 Because of the flexibility and resilience of the split
24 retention ring, the mating parts do not require fine tolerances

1 and are less expensive to make. Further, the split retention
2 ring provides infinite adjustment of the locking pressure as
3 the toggle bolt is tightened into the assembly. The system is
4 modular, employing a collection of anchoring assemblies that
5 are linked, via various connectors, to strategically-arranged
6 stabilizing rods. The stabilizing rods are shaped and aligned
7 to impart a preferred curvature to a patient's spine.

8 The anchoring assemblies are multi-piece units
9 characterized by linking members that are joined in a ball-and-
10 socket-type arrangement with a corresponding bone-engaging
11 member. During use, the bone-engaging member is secured to a
12 spinal bone and the linking member is secured to one of the
13 stabilizing rods via a corresponding connector. The bone-
14 engaging member may include coarse, external threads or have a
15 hook-shaped end. Each anchoring assembly also includes a
16 support collar that provides a secure interface between the
17 bone-engaging member and associated connector. Each anchoring
18 assembly also includes a securing nut and a locking bolt that
19 cooperate to prevent unwanted, post-installation motion within
20 the anchoring assembly. The securing nut and locking bolt also
21 prevent unwanted relative motion between the anchoring assembly
22 and associated connector.

23 The connectors are rigid structures adapted to link an
24 associated anchoring assembly with one of the stabilizing rods.

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1 In one embodiment, the connectors are two-piece constructions
2 that allow the connector to engage a stabilizing rod in a
3 sandwich-type arrangement, permitting connector installation
4 and removal that does not disturb adjacent connectors.

5 The stabilizing rods are rigid members shaped to form a
6 spine-curvature-correcting path. Attaching each anchoring
7 assembly, via connectors, to a stabilizing rod forces a
8 patient's back into a surgeon-chosen shape. Stabilizing rods
9 may be used singly, or in pairs, depending upon the type of
10 correction required. The rods vary in size, but typically
11 extend between at least two vertebrae.

12 Thus, it is an objective of the present invention to
13 provide a bone screw assembly for a spinal fixation system that
14 permits component adjustment during installation, thereby
15 enabling satisfactory correction of a wide variety of spinal
16 deformities.

17 It is an additional objective of the present invention to
18 provide a bone screw assembly that includes a split ring
19 locking mechanism that is simple and reliable. The split ring
20 has a tapered aperture and a spherical outer surface to mate
21 with the tapered end of a toggle bolt.

22 It is a further objective of the present invention to
23 provide a spinal fixation system that includes two-piece
24 connectors that may be mounted along, and removed from, a

1 support rod without requiring movement of adjacent connectors.

2
3 It is yet another objective of the present invention to
4 provide a spinal fixation system that includes mounting
5 hardware which requires a minimum number of tools.

6 It is also an objective of the present invention to
7 provide a spinal fixation system that allows modular
8 replacement of damaged components.

9 Other objects and advantages of this invention will become
10 apparent from the following description taken in conjunction
11 with the accompanying drawings wherein are set forth, by way of
12 illustration and example, certain embodiments of this
13 invention. The drawings constitute a part of this
14 specification and include exemplary embodiments of the present
15 invention and illustrate various objects and features thereof.
16
17

1 Brief Description of the Drawings

2 Figure 1 is a pictorial view of the spinal fixation system
3 of the present invention;

4 Figure 2 is a perspective view of an anchoring assembly
5 used in the present spinal fixation system;

6 Figure 3 is a cross section of the connector of this
7 invention;

8 Figure 4 is a perspective of the split ring connector; and

9 Figure 5 is a perspective view of an the toggle bolt of
10 the present invention.

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1 Detailed Description of the Preferred Embodiment

2 It is to be understood that while a certain form of the
3 invention is illustrated, it is not to be limited to the
4 specific form or arrangement of parts herein described and
5 shown. It will be apparent to those skilled in the art that
6 various changes may be made without departing from the scope of
7 the invention and the invention is not to be considered limited
8 to what is shown in the drawings and described in the
9 specification.

10 Now with reference to Figure 1, the spinal fixation system
11 10 of the present invention is shown. By way of overview, the
12 Fixation System 10 includes a collection of bone-engaging
13 anchoring assemblies 12 that are joined via connectors 14, 14'
14 to stabilizing rods 16, 16'. The specifics of the spinal
15 fixation system 10 will now be discussed in more detail.

16 With additional reference to Figure 2, one of the included
17 anchoring assemblies 12 is shown in an assembled state. Each
18 anchoring assembly 12 also includes a pedicle screw 20, a
19 toggle bolt 22, and a split retention ring 24. Each pedicle
20 screw 20 also includes a ball end 28 spaced apart from the
21 threaded end 26 by a neck portion 30. The exterior 32 of the
22 pedicle screw ball end 28 is preferably contoured for easy
23 grasping. The interior of the pedicle screw ball end 28 forms
24 a retention cavity 34, discussed below. The entrance 36 to the

1 retention cavity 34 is characterized by a securing lip 38 that
2 extends radially into the retention cavity 34.

3 Each toggle bolt 22, as shown in Figure 5, includes a
4 tapered end 40 and an opposite threaded end 42. As seen in
5 Figure 3, the tapered end 40 of the toggle bolt 22 is shaped
6 and sized to fit inside the pedicle screw retention cavity 34.
7 Preferably, the interior of the retention cavity is
8 substantially spherical but of larger dimensions than the
9 tapered contour of the toggle bolt end 40.

10 With reference to Figure 4, the split retention ring 24
11 has a substantially spherical outer surface and a tapered inner
12 wall. The ring includes a gap 44 separating the opposite ends
13 of the split retention ring main body 46. As seen in Figure 3,
14 the split retention ring 24 is used as a bracing means to
15 secure the tapered end 40 of the toggle bolt 22 within the
16 pedicle screw retention cavity 34. More specifically, after
17 the toggle bolt tapered end 40 is placed within the pedicle
18 screw retention cavity 34, the split retention ring 24 is
19 placed about the shank of the toggle bolt and pushed through
20 the entrance 36 of the retention cavity 34 by reducing the gap
21 44 facilitating travel past the engagement lip 38, thereby
22 bringing the split retention ring main body 46 to rest against
23 the engagement lip by spring action resilience of the split
24 retention ring 24.

1 With this arrangement, the split retention ring 24 allows
2 universal movement of the toggle bolt 22 within the retention
3 cavity 34, while preventing removal of the toggle bolt
4 therefrom. Once the split retention ring 24 and toggle bolt 22
5 are in place, the threaded end 42 of the toggle bolt is
6 inserted through a passthrough aperture of the support collar
7 18 (not shown).

8 Once the toggle bolt 22 has been passed through the
9 support collar, the support collar comes to rest against the
10 pedicle screw ball end 28. Although several shapes are
11 possible, the interior of the support collar preferably has a
12 spherical contour that matches the exterior 32 of the pedicle
13 screw ball end 28. This arrangement limits the relative motion
14 possible between the support collar and the toggle bolt 22,
15 while allowing the split ring 24 to rotate freely within the
16 pedicle screw retention cavity 34. Although an assembly
17 process has been described above, the anchoring assemblies 12
18 are typically delivered to the end-user surgeon as a finished
19 unit.

20 *chart* With additional reference to Figure 3, the threaded
21 interior bore 122 of the toggle bolt threaded end 42 has a
22 hexagonal cross section. This allows the insertion of an allen
23 wrench, not shown, into the interior bore 122 to hold the
24 connection and prevent relative motion between the tapered end

1 40 of the toggle bolts 22 and the spherical retention cavity 34
2 of the pedicle screw 20. The inserted allen wrench thereby
3 prevents unwanted spinning of the toggle bolt 22 within the
4 retention cavity 34 while the securing nut 116 is tightened
5 onto the exterior threads 120.

6 Tightening the securing nut 116 forces the toggle bolt
7 threaded end 42 to travel longitudinally through the
8 passthrough aperture (not shown) and also causes the toggle
9 bolt tapered end 40 to be forced against the split retention
10 ring 24 with the longitudinal movement reducing the gap 44.
11 Further tightening of the securing nut 116 forms a
12 substantially rigid fit between the toggle bolt 22 and the
13 pedicle screw 20. With the securing nut 116 tightened
14 appropriately, the toggle bolt threaded end 42 is locked in
15 place with regard to the right-facing straight connector
16 attachment flange, and the toggle bolt tapered end 40 is locked
17 in place within the pedicle screw retention cavity 34. In this
18 state, the split retention ring is sandwiched between the
19 exterior of the toggle bolt ball end 40 and the ball-shaped
20 interior of the retention cavity 34. Since the split retention
21 ring 24 is locked within the retention cavity 34 by the
22 retention cavity engagement lip 38, relative motion between the
23 toggle bolt tapered end and the pedicle screw 20 is prevented
24 once the toggle bolt threaded end 42 is locked in place by the

1 tightened securing nut 116. This results in a rigid link
2 between the right-facing straight connector and the anchoring
3 assembly 12.

4 Although the above description refers to joining an
5 anchoring assembly 12 specifically to a right-facing straight
6 connector 52, each of the one-piece connectors 14 and two-piece
7 connectors 14' may be attached to an anchoring assembly in a
8 similar manner. That is, right-facing offset connectors are
9 attached by inserting a toggle bolt threaded end through the
10 associated passthrough aperture ; left-facing offset connectors
11 are joined with an anchoring assembly by inserting a toggle
12 bolt threaded end through an associated passthrough aperture;
13 and left-facing straight connectors are attached to anchoring
14 assemblies by inserting a toggle bolt threaded end through an
15 associated passthrough aperture. In each case, the exterior
16 threads 120 of the inserted toggle bolt threaded end 42 are
17 held in place by a tightened securing nut 116, as described
18 previously.

19 To prevent unwanted loosening of a connector 14, 14' and
20 anchoring assembly 12 union, a locking bolt 118 is inserted
21 into the threaded interior bore 122 of the toggle bolt
22 corresponding to each anchoring assembly that has been secured
23 in place. As mentioned above, each locking bolt 118 has a
24 left-handed thread pattern, thereby matching the left-handed

1 thread pattern of each toggle bolt threaded interior bore 122.
2 The locking bolt 118 is screwed into an associated toggle bolt
3 threaded interior bore 122 until the locking bolt head plate
4 comes to rest against the securing nut 116 that holds the
5 corresponding anchoring assembly 12 in place with respect to
6 the associated connector 14, 14'. Incorporating this locking
7 bolt 118 ensures that anchoring assemblies 12 and connectors
8 14, 14' stay locked in place, thereby preventing unwanted
9 relative motion within the spinal fixation system 10.

10 In all other respects, the split ring bone screw of this
11 invention may be deployed with other fixation apparatus as
12 shown and described in the parent application, S. N.
13 09/981,961, incorporated herein by reference.

14 Although the invention has been described in terms of a
15 specific embodiment, it will be readily apparent to those
16 skilled in this art that various modifications, rearrangements
17 and substitutions can be made without departing from the spirit
18 of the invention. The scope of the invention is defined by the
19 claims appended hereto.